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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,874	09/05/2003	Richard L. Gehant	11669.121USU1	7188
23552	7590	09/13/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/655,874

Applicant(s)

GEHANT, RICHARD L.

Examiner

Hope A. Robinson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 19-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 4-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/21/04, 3/3/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Applicant's election with traverse of Group I (claims 1-18) filed on April 12, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 19-43 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

2. Applicant's comments regarding a rejoinder of a product made by the elected method upon notification of an allowance is noted. It is noted that applicant cites MPEP 821.04 in support of this request. However, applicant's statement is not accurate as the MPEP states that "if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined".

Specification

3. The specification is objected to because of the following informalities:

(a) The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademarks such as SEPHAROSE™ for example, have

been noted in this application (see page 16). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Correction is required.

Drawing

4. It is noted that this application contains drawings executed in color.

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Correction is required.

Claim Objection

5. Claims 1, 3 and 18 are objected to because of the following informalities:

(A) Claim 1 is objected to because the spelled out meaning for the abbreviation "*E. coli*" does not appear in the claim, it is suggested that the claim is amended to recite "*Escherichia coli*".

For clarity it is suggested that the preamble of the claim recite "heterologous target protein" as recited in steps (a and c). Additionally, to clarify the language in the claim it is suggested that step (b) is amended to read: "disrupting the cells to release the heterologous target protein" and step (c) is amended to read, "separating cellular debris from the released heterologous target protein to obtain a protein product enriched in said heterologous target protein".

(B) Claim 3 is objected to because the claim does not further limit claim 2 as a pH of "about 4.0 to about 5.0" would also be a pH of "about 4.0 to about 4.5." Note that the instant specification on page 4 discloses that "about" generally refers to a range of numbers that one would consider equivalent to the recited value". It is suggested that the term "about" is deleted from the claims.

(C) Claim 18 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 8. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Note that claims 8 and 18 depend from

claim 7 (which encompasses the limitations of claims 1, 5 and 6) and both claims indicate the use of expanded bed chromatography.

(D) Claims 4-17 are objected to because the claims depend from a rejected based claim.

Correction of the above is required.

Information Disclosure Statement

6. The Information Disclosure Statements filed on January 21, 2004 and March 3, 2004 have been received and entered. The references cited on the PTO-1449 Forms have been considered by the examiner and a copy is attached to the instant Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by IMMUNEX CORPORATION (WO 88/01624, March 10, 1988).

IMMUNEX CORPORATION teaches a process for extraction of a protein from *E. coli* (claim 1, see page 3, lines 1-2 and line 9 of the reference). The steps employed in the process include: suspending the cells in a solution having a pH about 1 to about 5 (acidic); disrupting the cells to provide an extract containing the protein and recovering the protein from the extract (claim 1, see page 2, lines 23-27 of the reference). IMMUNEX CORPORATION also teach that the acid extraction step is preferably conducted at a pH from about 3.5 to about 4.5 (claims 2-3, see page 3, lines 34-36). Therefore, the limitations of the claims are met by the reference.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Nye et al. (Molecular Immunology, vol. 32, no. 14, pages 1131-1141, 1995).

Nye et al. teach extraction of a protein from *E. coli* cells by simultaneous acid solubilization and mechanical disruption and separation via chromatography (claim 1, see page 1135, column 1, paragraphs 1 and 2). Therefore, the limitation of the claim is met by the reference.

Conclusion

9. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS ^{HRS}
9/3/04
Patent Examiner